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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,508	01/08/2002	Thomas O. Murdock	ARC 2452D1	7206

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EXAMINER	
MICHENER, JENNIFER KOLB	
ART UNIT	**PAPER NUMBER**
1762	

DATE MAILED: 08/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/042,508	MURDOCK, THOMAS O.	
	Examiner	Art Unit	
	Jennifer K. Michener	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 30-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 30-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 34, 36, and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

These claims require a dry state electrode assembly, however, the electrode assembly described in the specification, particularly outlined in reference to Figure 2 a-c, contains a hydrogel layer, which would not appear to be "dry". All possible configurations disclosed for Applicant's assembly include this hydrating (i.e., non dry) material.

Also, based upon description in the specification, a hydrating agent must be present to act on the hydratable agent-containing matrix in order for the agent to be released to the body. Since Applicant's background teaches against the use of body sweat, etc. as such a hydrating agent as it is too time-consuming, Applicant's specification appears to require the hydrogel. Thus, one is not enabled to create the assembly in a dry state.

3. Claims 35, 37, and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It appears that the language regarding a self-contained electrode assembly unit including anode, cathode, and power source is new matter. Examiner is unable to find basis for this language in the originally-filed disclosure. Additionally, it seems to contradict the definition of "electrode assembly" as provided for in the specification which includes more than the elements now claimed.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 36 requires a dry state assembly, but this claim depends on claim 33, which has a hydrating later within the assembly, which would not appear to be "dry". This is contradictory and confusing.

Examiner notes that upon clarification of the 112 issues, above, a restriction requirement may be made by Examiner if it becomes clear that Applicant is pursuing a set of claims directed to an assembly with a hydrating component and another set of claims directed to a "dry" assembly. These represent distinct species.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-2, 6-7, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Higo et al. (US 5,908,400).

Higo et al. discloses a method of forming an anhydrous reservoir layer of an electrode assembly in an electrically powered electrotransport agent delivery device, the reservoir layer having a matrix and being adapted to be placed in agent-transmitting relation with a body surface and an electrode in electrical contact with a power and the reservoir layer, comprising the steps of: dissolving a beneficial agent in a solvent, and applying the solvent and dissolved beneficial agent to a surface of a hydrophilic polymer filtration membrane (col. 14, lines 44-49); removing the solvent from the filtration membrane forming a hydratable agent-containing filtration membrane 8 (col. 15, lines 51-62); and disposing the hydratable agent-containing matrix 8 within the electrode assembly (col. 6, line 66 to col. 7, line 4). It is known that the drug holder or retainer layer of Higo et al. is a filtration membrane because Higo et al. teaches that the drug holder or retainer layer has a porous or capillary structure, having pore sizes similar to those taught in the specification, and made of similar polymeric materials as those

taught in the specification, including the use of hydrophilic polymers (col. 9, line 59 to col. 10, line 34). Additionally, Higo et al. teaches that the drug layer is present in a dry condition and is hydrated when brought into contact with the hydrophilic, polymeric gel layer, just as is taught by Applicant, so that the drug in the drug layer is dissolved, therefore the drug layer also is a hydratable matrix (col. 7, lines 38-41).

As to claim 2, Higo et al. teaches dissolving the drug/agent in water, which is an aqueous based solvent (col. 14, lines 44-45).

As to claim 6, Higo et al. teaches that the drug retainer layer 8, or filtration membrane, may be made of polysulfone in col. 10, line 7.

As to claim 32, it is noted that Higo et al.'s hydrophilic, polymeric gel layer is a "hydrating material" and is located between the electrode and the hydratable agent-containing matrix.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 3-5, 8-11, 30-31, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higo et al.

Higo et al. is applied for the reasons discussed above in section 3.

As to claims 3-4, Higo et al. lacks a teaching of using ethanol or isopropanol as the solvent for dissolving the drug in the porous drug retainer layer. It is well known in the art that ethanol and isopropanol are two aqueous solvents compatible with the body, in addition to water. It would have been obvious for one having ordinary skill in the art to have substituted, or added, another aqueous solvent other than water that is also compatible with the body, such as ethanol or isopropanol, with the expectation of similar and successful results.

As to claim 5, Higo et al. broadly teaches using "porous polysulfones" as the material for the drug retainer layer, however does not provide specific polysulfone materials. It would have been obvious for one skilled in the art to have selected a known porous polysulfone material that is generally low in adsorption of drugs, such as polyether sulfone, for use as the drug retainer material in Higo et al.'s process with the expectation of successful results since Higo et al. generally discloses use of polysulfones and is not limiting.

As to claims 8-11, Higo et al. discloses drying the membrane/drug retainer layer so that the drug-retaining layer is "well dried" (col. 15, lines 51-58). It would have been obvious for one skilled in the art to have used conventional drying means, such as a forced air oven, vacuum drying oven, desiccator, or lyophilization, in order to dry the drug-retaining layer since Higo et al. is silent and not limiting with respect to specific drying means.

As to claims 30-31 and 33, Higo et al. is silent with respect to the amount of residual moisture content in the hydratable drug-retaining layer. However, Higo et al.

states that the layer should be "well dried," and teaches use of a drying agent to ensure the dryness during packaging/storage. Therefore, Higo et al. would have clearly suggested to one skilled in the art to have completely dried the drug-retaining layer, for example to less than 5% or 1%, in order to achieve optimal results. Further, as to claim 33, Higo et al. teaches that the drug-retaining layer has a thickness in the range of 1-500 μm, or 0.04-20 mils. Overlapping ranges are *prima facie* evidence of obviousness. It would have been obvious to one having ordinary skill in the art to have selected the portion of Higo et al.'s thickness range that corresponds to the claimed range. *In re Malagari*, 184 USPQ 549 (CCPA 1974).

Response to Arguments

10. Applicant's arguments filed 6/16/2005 have been fully considered but they are not persuasive.

Applicant argues that the drug layer of Higo is attached to the device and is separate from the reservoir portion, so cannot reasonably be considered a reservoir layer as claimed.

Examiner notes that Applicant seems to be making a distinction between Higo's drug reservoir coating and Higo's "reservoir" (i.e., a type of vessel) that holds the hydrophilic polymeric gel.

It is well-known in the art that a drug reservoir layer is a layer not a container or vessel or "reservoir" of some sort. Examiner does not rely on the structure that holds the hydrogel in Hilgo to teach the limitations of the drug-retaining membrane (Hilgo's

equivalent to Applicant's drug reservoir layer). Referring to Figure 2(b), Applicant's therapeutic polymer layer (the drug reservoir layer), 36 is attached proximate to the skin below a layer of hydrating hydrogel material, 38, with an electrode layer, 22, above the hydrogel layer. Layers 36, 38, and 22 make up Applicant's electrode assembly, 12. Likewise, Higo's drug layer, 8, is attached to the hydrogel, 4, which lies between the drug layer, 8, and the electrode layer, 3. Higo's drug layer is distinct just as Applicant's is. It is most reasonably considered the reservoir layer of Applicant, as it is made in the same way, attached to the rest of the electrode assembly in the same way, and is used in the same way on a human body.

Applicant argues that Higo's hydrogel surrounds the electrode, which has shortcomings. Examiner notes that Applicant's hydrogel contacts his electrode as well.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Tuesdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy H. Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer K Michener
Primary Patent Examiner
Art Unit 1762
August 14, 2005

jkm